

REMARKS

An Office Action mailed June 16, 2005 has been received and reviewed. Claims 1-35 are pending. No claims have been amended. Favorable consideration of the application is respectfully requested in view of the following remarks.

Claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Salo et al.*, US 5,728,140 (hereinafter *Salo*), in view of *Helland et al.*, US 5,545,210 (hereinafter *Helland*).

To establish *prima facie* obviousness of Applicant's claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (*see, e.g.*, MPEP § 2142).

The Examiner contends that *Salo* discloses the invention substantially as claimed, but that *Salo* fails to teach what type of insulation is used. Applicant respectfully disagrees that *Salo* substantially teaches Applicant's invention, as set forth, for example, in independent claims, 1, 6, 14, 19, 24, and 30. Each of these claims recites, in some form, a pacing electrode having a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the electrode sufficient in coverage to inhibit exit block development.

In contrast to the above claims, *Salo* teaches "a rigid helix similar to a corkscrew that has a proximal portion thereof coated with insulation but whose distal convolution(s) are bare and form an electrode surface" (col. 1 lines 59-63). At col. 2 lines 52-54, *Salo* describes "lead 12 has a conductive, relatively rigid helix 16 at the distal end thereof which terminates in a tissue-piercing tip 18" (col. 2 lines 52-54). *Salo* states "all but a predetermined number of convolutions of the helix have their surface coated with an insulating layer and only the most distal convolutions are free of insulation and thereby

function as a tissue stimulating surface or electrode” (col. 2 lines 57-61). (emphasis added) *Salo* teaches that the rigid helix has an insulating layer. The electrode taught by *Salo* includes only the “most distal convolutions” which are “free of insulation.” The electrode taught by *Salo*, i.e., the tissue stimulating surface, does not have a coating or sleeve as in Applicant’s claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33.

Helland does not cure the deficiencies of *Salo*. As set forth in Applicant’s response to the last Office Action, *Helland* does not teach or suggest a coating or sleeve provided on a majority of the exposed surface of the fixation arrangement. *Helland* discloses a bipolar active fixation lead having a helix 44 defining an inner electrode 46, an intermediate insulator 48, and an outer electrode 50, as shown in Figures 3-5 of *Helland*. The outer and central electrodes 50, 46 operate as a bipolar electrode pair. As can be seen in Figures 3-5 of *Helland*, the intermediate insulator 48 does not cover a majority of the exposed surface of the fixation member. The inner 46 and outer 50 electrodes form the majority of the exposed surface of *Helland*’s fixation member and these elements are not covered by the insulator.

Neither *Salo* nor *Helland* teach or suggest all of the claims limitations of Applicant’s claims. Because the references cited by the Examiner do not teach or suggest all of the claim limitations, Applicant’s claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33 are patentable over the combination of *Salo* and *Helland*.

Further, *Salo* expressly teaches that the electrode is not covered by insulation. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). The references cited by the Examiner fail to suggest the desirability of the combination and provide no motivation to make the asserted combination as required to establish a *prima facie* case of obviousness. For at least these reasons, claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33 are patentable over the combination of *Salo* and *Helland*.

Claims 2, 4, 7, 9, 15, 17, 20, 22, 26, 28, 32, and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Salo* in view of *Helland* and in further view of Carson, US 5,931,862. Claims 5, 10, 18, 23, 29, and 35 are rejected under 35 U.S.C. §

103(a) as being unpatentable over *Salo*, in view of *Helland*, and in further view of Stokes, H356.

Each of the above-listed obviousness rejections relies on the teachings of *Salo* and *Helland*. Applicant asserts that the additional references, when combined with *Salo* and *Helland*, fail to render the claims listed above unpatentable. A *prima facie* case of obviousness requires that the asserted references teach or suggest all of the claim elements. In each of the combinations asserted above, none of the asserted references (*Salo*, *Helland*, *Carson*, *Stokes*) teaches or suggests, for example, an electrode having a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the electrode.

Neither *Salo* nor *Helland* describes this element for the reasons discussed above. *Carson* expressly teaches that portions of lead 12 not covered by the sheath include the distal pacing electrode 20, which is shown to include a helix or tine fixation element. See *Carson*, column 4, lines 34-36. *Stokes* describes a pacing lead that has a bore for passage of a drug to the stimulation and fixation site. The fixation element in *Stokes* does not have a coating or sleeve. Because, for each rejection made by the Examiner, the cited references do not teach or suggest all of the claim limitations of Applicant's invention, claims 2, 4, 5, 7, 9, 10, 15, 17, 18, 20, 22, 23, 26, 28, 29, 32 and 35 are patentable over the asserted combinations.

It is to be understood that Applicant does not acquiesce to Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicant's claimed subject matter. Applicant reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

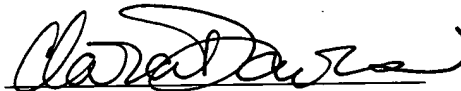
It is believed that the pending claims as amended are in condition for allowance and removal of the finality of the rejection is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,

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Date: November 15, 2005

By:

A handwritten signature in black ink, appearing to read 'Clara Davis', written over a horizontal line.

Clara Davis
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